K113766

PREMARKET NOTIFICATION

MAR 16 2012

510(k) Summary

VariSource Transfer Guide Tube Sets

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA94304 Contact Name: Ms Vy Tran, VP, QA/RA Phone: 650/424.5731 Fax:650/842.5040 vy.tran@varian.com Date: 15 December 2011
Proprietry Name:	VariSource Transfer Guide Tube Sets.
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Guide Tubes, Connecting Tubes, Transfer Guide Tubes, Connecting Catheters, Reusable Transfer Guide Tubes.
Predicate Devices:	K952913 Applicators for Varian VariSource Remote HDR afterloader
Device Description:	Transfer Guide Tubes are designed to provide a secure connection between the VariSource afterloader and applicators, needles or catheters along which the source wire travels during Brachytherapy. Each Transfer Guide Tube has an appropriate connection at one end for the Varisource Afterloader and at the other end a connection for an applicator, needle or catheter.
Indications for Use:	The VariSource Reusable Transfer Guide tubes are intended to connect between the VariSource Remote HDR Afterloader system and its range of applicators. This connection creates a conduit for

the source wire to travel through and allows radioisotopes to be positioned within the patient's tumour site.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION K952913	DEVICE WITH CHANGE
Intended Use/Indications for Use	Covered by intended use of complete afterloader system in original submission.	The VariSource Reusable Transfer Guide Tubes are intended to connect between the VariSource Remote HDR Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows radioisotopes to be positioned within the patient's tumour site.
Material	**Coupling Catheter:** polytetrafluoroethylene (PTFE) or Nickel Titanium (Information from Feature Comparison Sheets for FSD covered by K952913).	Fluorinated Ethylene Propylene (FEP).
Number of Uses.	**Coupling Catheter** -Single Use (PTFE) Multiple Use (Nickel Titanium) (From Data Sheets for applicators covered by K952913).	Multiple Use.
Sterilization	**Coupling Catheter** ETO or Autoclave- Nickel Titanium ETO- PTFE (From Data Sheets for applicators submitted for K952913).	None (No body contact)
Fitting	Screw thread	ClickFit/ClickFit Needle/Catheter/Luer

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION K952913	DEVICE WITH CHANGE
Closed or opened ended when not attached	Open	Closed(ClickFit/Clickfit Needle)
Other technical changes - manufacturing	Wire channel screwed and bonded into QuickConnect	Wire channel moulded directly into QuickConnect
Other technical changes - manufacturing	Original tolerance level for internal diameter on Quick Connect to accommodate thread insert for the tube. (Ø 5 ±0.1mm).	Changed tolerance level for internal diameter on Quick Connect to accommodate thread insert for the tube (Ø 5,2 ±0.05mm). Change made for easier assembly during manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Systems
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304

MAY 17 2012

Re: K113766
Trade/Device Name: Transfer Guide Tubes
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: December 15, 2011
Received: December 21, 2011

Dear Ms. Tran:

This letter corrects our substantially equivalent letter of March 16, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use Form

510(k) Number (if known): K113766

Device Name: **Transfer Guide Tubes**

Indications for Use:

The Varisource Reusable Transfer Guide Tubes are intended to connect between the Varisource Remote HDR Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows radioisotopes to be positioned within the patient's tumour site.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113766